REMARKS

This responds to the Office Action mailed on March 13, 2009.

Claims 1, 18, 30, 33, and 35-37 are amended, claims 6-10 are canceled, and claims 46-49 are added; as a result, claims 1-5 and 11-49 are now pending in this application.

Interview Summary

Applicant thanks Examiner Joseph Burgess and Supervisory Patent Examiner Luke Gilligan for the courtesy of a telephone interview on June 4, 2009 with Applicant's representatives John I. Fischer and Suneel Arora. During the interview, Applicant's disclosure was discussed with respect to proposed claims and the references of record. Examiners Burgess and Gilligan appeared to agree that the present amendments overcame the present art of record. However, Examiner Burgess indicated that a new search would be performed.

§ 101 Rejection of the Claims

Claims 30-35 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant has amended claims 30 and 35 to overcome these rejections.

In particular, in claim 30, Applicant has amended the preamble to recite a "tangible computer useable storage medium." Applicant respectfully submits that this preamble omits signals from the scope of this claim, thereby casting the claim to recite proper statutory subject matter.

In claim 35, Applicant has revised the preamble to recite a computer usable storage medium instead of a signal. As such, Applicant respectfully submits that the amended claim recites proper statutory subject matter.

In sum, Applicant respectfully submits that claims 30 and 35 as currently presented encompass statutory subject matter and request reconsideration and withdrawal of the § 101 rejections of these claims and any dependent claims derived therefrom.

§ 112 Rejection of the Claims

1.   Claims 6, 8-10 and 33 were rejected under 35 U.S.C. § 112, first paragraph, for lack of adequate description or enablement.

Claims 6 and 8-10 have been canceled, thereby rendering the rejection of these claims moot. With respect to claim 33, Applicant respectfully submits that in the context of claim 33, installation of a medical device may include providing programming parameters before, during or after an implant procedure. For example, as described at ¶ 0043 of the published application: "Programming instructions, including operating values, are also sent to the processor 114 within the medical device 102 as part of the initialization and installation process." Applicant respectfully submits that "initialization" and "installation" are similar and may overlap in scope, within the context of claim 33. However, to expedite prosecution of these claims, Applicant has removed the recitation related to "installation," thereby obviating the basis of the rejection of claim 33. Thus, Applicant respectfully submits that claim 33 conforms to the requirements of § 112 and requests reconsideration and withdrawal of the rejection of claim 33.

2.   Claims 1, 18, 33, 37 and 40 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

With respect to claim 1, Applicant has amended claim 1 to remove the disjointed phrase.

With respect to claim 18, Applicant has amended claim 18 to recite the "computing device" as is recited in other portions of the same claim.

With respect to claim 33, as discussed above, Applicant respectfully submits that in the context of claim 33 and in view of the specification, the term "installation" is understood to include causing a computer to install a medical device, such as, for example, by providing programming instructions to the processor of a medical device. Moreover, canceled claim 8 recited "wherein installing the medical device comprises implanting the medical device in a patient." Although this claim has been canceled, it clearly illustrates Applicant's intent that "installation" is broader than "implantation." As discussed, the broader scope may be directed to programming instructions, for example. Thus, Applicant respectfully submits that there is sufficient support in the specification for the claim as originally-filed. However, to expedite prosecution of this claim, Applicant has removed the recitation related to "installation", thereby rendering the rejection of this claim moot.

With respect to claim 37, Applicant has amended this claim to revise the use of "any" to "a".

AMENDMENT AND RESPONSE UNDER 37 C.F.R § 1.111
Serial Number:10/829,547
Filing Date: April 22, 2004
Title: PROVIDING AND COMMUNICATING DATA MESSAGE ALERTS STORED ON MEDICAL DEVICES

Page 14
Dkt: 279.B44US1

With respect to claim 40, Applicant respectfully directs the Examiner to the application where various means for inputting the data message alert are described. For example, at ¶ 0045 of the published application, Applicant provides:

> At receive operation 310 a data message alert is received from a user via at least one input device. For instance, the user may input the data message alert as text via use of the keyboard 172. The user may also record the data message alert as an audio message via the audio input device 122.

In addition, at ¶ 0026, the published application describes:

> The programmer 101 that is shown includes an input/output controller 224 (see FIG. 2) interfaced with a number of input devices. The input devices include, but are not limited to, a keyboard 172, an audio input 122, and a stylus 125, that allow the user to input information such as data message alerts and function selections.

In sum, Applicant respectfully submits that the claims as currently presented address the § 112 issues raised by the Examiner. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 112 rejections of these claims.

§ 103 Rejection of the Claims

1.   Claims 1-6, 8, 11-14, 16-20, 22, 23 and 25-45 were rejected under 35 U.S.C. § 103(a) for obviousness over Levine et al. (U.S. Patent No. 6,327,501) in view of Linberg et al. (U.S. Patent No. 6,497,655).

Concerning independent claims 1, 30 and 36:

Applicant cannot find in the cited portions of Levine or Linberg any disclosure of "receiving, at a computing device from a user of the computer device, a data message alert including at least in part user-supplied narrative data," as presently recited in claim 1, and similarly recited in claims 30 and 36. Instead, it appears that Levine refers to "safety alert information," which may be provided by "a manufacturer may send a computer diskette containing the safety alert advisory to all of the known practitioners who have external programmers **32**," "the external programmer **32** periodically retrieves safety alert data from one

or more predefined or other web sites on the Internet, a local network or the like" or "the medical

practitioner inputs the safety alert data via the user input device **62** into the memory storage **56** of

the external programmer **32** after receipt of a written safety alert bulletin from the manufacturer."

Levine at col. 11, lines 13-38. Applicant respectfully submits that Levine's safety alert

information is not "user-supplied narrative data," as presently recited in claim 1 and similarly

recited in claims 30 and 36.

Thus, because Levine, Linberg, and the reasoning of the Office Action fail to establish all

elements of claims 1, 30, and 36, no *prima facie* case of obviousness exists for these claims.

Consequently, Applicant respectfully requests reconsideration and withdrawal of this rejection of

these claims.

Concerning independent claim 35:

Applicant cannot find in the cited portions of Levine or Linberg any disclosure of

"receive a data message alert via a programmer, the data message alert including at least in part a

user-recorded audio message," as presently recited in claim 35. Instead, as discussed above, it

appears that Levine refers to "safety alert information," which may be provided by "a

manufacturer may send a computer diskette containing the safety alert advisory to all of the

known practitioners who have external programmers **32**," "the external programmer **32**

periodically retrieves safety alert data from one or more predefined or other web sites on the

Internet, a local network or the like" or "the medical practitioner inputs the safety alert data via

the user input device **62** into the memory storage **56** of the external programmer **32** after receipt

of a written safety alert bulletin from the manufacturer." Levine at col. 11, lines 13-38.

Applicant respectfully submits that Levine's safety alert information is not "at least in part a

user-recorded audio message," as presently recited in claim 35.

Moreover, Applicant cannot find in the cited portions of Levine or Linberg any disclosure

of "upon interrogating the medical device, communicating the data message alert via the

programmer and playing the user-recorded audio message..." as presently recited in claim 35.

As neither Levine nor Lindberg apparently refer to storing audio information on a medical

device, it is clear that neither reference can disclose "upon interrogating the medical device,

AMENDMENT AND RESPONSE UNDER 37 C.F.R § 1.111
Serial Number:10/829,547
Filing Date: April 22, 2004
Title: PROVIDING AND COMMUNICATING DATA MESSAGE ALERTS STORED ON MEDICAL DEVICES

Page 16
Dkt: 279.B44US1

communicating the data message alert via the programmer and playing the user-recorded audio message," as recited in claim 35.

Thus, because Levine, Linberg, and the reasoning of the Office Action fail to establish all elements of claim 35, no *prima facie* case of obviousness exists for this claim. Consequently, Applicant respectfully requests reconsideration and withdrawal of this rejection of this claim.

Concerning dependent claims:

Applicant has canceled claims 6 and 8 thereby obviating the rejection of these claims.

Applicant respectfully submits that the dependent claims 2-5, 11-14, 16-20, 22, 23 and 26-29, 31-34, and 37-45 depend directly or indirectly from independent claims 1, 30 or 36, respectively. As such, these dependent claims incorporate all the recitations of claims 1 or 34. Accordingly, Applicant respectfully submits that these dependent claims are patentable for at least the reasons set forth above. Thus, Applicant respectfully requests withdrawal of this rejection of these claims. For brevity, Applicant reserves the right to present further remarks concerning the patentable distinctiveness of such dependent claims.

2.   Claim 7 was rejected under 35 U.S.C. § 103(a) for obviousness over Levine et al. in view of Linberg et al. in further in view of Mann et al. (U.S. Patent No. 5,833,623).

Applicant respectfully submits that the dependent claim 7 depends directly or indirectly from independent claim 1. As such, it incorporates all the recitations of claim 1. Accordingly, Applicant respectfully submits that claim 7 is patentable for at least the reasons set forth above, because Mann does not cure the defects with Levine and Linberg, as described above. Thus, Applicant respectfully requests withdrawal of these rejection of claim 7. For brevity, Applicant reserves the right to present further remarks concerning the patentable distinctiveness of this dependent claim.

3.   Claims 9, 10, 15 and 21 were rejected under 35 U.S.C. § 103(a) for obviousness over Levine et al. in view of Linberg et al. in further in view of Official Notice.

Applicant has canceled claims 9 and 10 thereby rendering the rejection of claims 9 and 10 moot .

Moreover, Applicant respectfully submits that the dependent claims 15 and 21 depend directly or indirectly from independent claim 1. As such, these dependent claims incorporate all the recitations of claim 1. Accordingly, Applicant respectfully submits that these dependent claims are patentable for at least the reasons set forth above because the Official Notice does not cure the defects with Levine and Linberg, as described above. Thus, Applicant respectfully requests withdrawal of these rejection of these claims. For brevity, Applicant reserves the right to present further remarks concerning the patentable distinctiveness of such dependent claims.

4.   Claim 24 was rejected under 35 U.S.C. § 103(a) for obviousness over Levine et al. in view of Linberg et al. in further view of Haller et al. (U.S. Patent No. 7,181,505).

Applicant cannot find in the cited portions of Levine, Lindberg, Haller, or the Office Action's reasoning, any disclosure of "wherein the data message alert comprises the message communicating that at least one of the medical device and the patient utilizing the medical device are enrolled in the clinical study," as recited in claim 24. Instead, the cited portions of Haller appear to merely refer to the use of implantable medical devices (IMDs) in clinical studies. Although Haller apparently refers to interrogating an IMD, stating "Devices 10, 100, and/or 110 are remotely interrogated using remote system 130 and communication system 120," Haller, does not disclose messages that "communicate that at least one of the medical device and the patient utilizing the medical device are enrolled in the clinical study," as recited in claim 24. In fact, Applicant respectfully submits that it would be unnecessary to do so in Haller as Haller's system would have prior knowledge that the IMD was enrolled in a clinical study before interrogating the IMD. Thus, one of ordinary skill in the art would not have any reason to modify Haller to provide a message of the type recited in claim 24.

Furthermore, Applicant cannot find in the cited portions of Levine, Lindberg or Haller or in the Office Action's reasoning any disclosure of "utilizing the data message alert to verify that at least one of the patient data and the medical device data are being uploaded to a correct study registry in the database for the clinical study," as recited in claim 24. Haller does not appear to describe any type of data verification. Moreover, as with the previous portion of claim 24 discussed above, upon review of Haller, there is no reason to perform a verification like the one

described in claim 24 because Haller's system has previous knowledge of the IMD it is interrogating

Applicant respectfully submits that the purported combination of Levine, Lindberg, and Haller, based on the Office Action's reasoning, would merely provide a system that may be capable of retrieving manufacturer alerts from IMDs implanted in patients who are in a clinical study. Clearly, there is a large gap between the purported combination of Levine, Lindberg, and Haller, and Applicant's claimed method recited in claim 24.

In sum, because Levine, Lindberg, Haller, and the Office Action's reasoning fail to establish all of the elements of claim 24, Applicant respectfully submits that a *prima facie* case of obviousness has not been established. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 24.

New Claims 46-49

Claims 46-49 have been added in this response. Support for claims 46-49 can be found throughout the originally-filed specification. For example, support for claim 46 can be found at least on page 13, lines 3-26; support for claim 47 can be found at least on page 8, lines 16-18; support for claim 48 can be found at least on page 8, lines 20-21, lines 26-27; and support for claim 49 can be found at least on page 8, lines 26-27. As such, Applicant respectfully submits that new claims 46-49 do not introduce any new matter. Applicant respectfully submits that claims 46-49 are allowable over the current references and requests notification of the same.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present

AMENDMENT AND RESPONSE UNDER 37 C.F.R § 1.111
Serial Number:10/829,547
Filing Date: April 22, 2004
Title: PROVIDING AND COMMUNICATING DATA MESSAGE ALERTS STORED ON MEDICAL DEVICES

Page 19
Dkt: 279.B44US1

claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date _June 10, 2009_   By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10th day of June, 2009.

Kate Gannon

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Name   Signature